

Atty Dkt. No.: L1111-009
USSN: 09/630,340

REMARKS

In view of the above amendments and the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow Claims 11-18.

Claims 11 and 15 have been amended to clarify the description of the means for collecting reflectance data.

Claims 19-22 have been cancelled.

As no new matter has been added by the above amendments, the Applicants respectfully request the entry thereof.

Rejection under 35 U.S.C. §112, Second Paragraph

Claims 19-22 have been rejected under 35 U.S.C. §112, second paragraph. Claims 19-22 have been cancelled. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Rejection under 35 U.S.C. §102(e)

Claims 11, 12, 14, 19, 20 and 22 have been rejected under 35 U.S.C. §102(c) as anticipated by U.S. Patent No. 6,084,660 issued to Sharlic. The Examiner contends that the cited reference discloses an automated meter useful in testing for the presence of a sufficient amount of sample on a test strip. The meter of the cited reference, the Examiner asserts, comprises the elements of Claims 11, 12, 14, 19, 20 and 22. As described above, Claims 19, 20 and 22 have been cancelled. In regards to Claims 11, and Claims 12 and 14 by virtue of their dependency from Claim 11, the Applicants submit that the cited reference does not anticipate these claims.

Claims 11, 12 and 14 specify an optical meter that includes a means that collects reflectance data from a region of the meter occupied by a sample application location of the test strip when a test strip is present in the meter over a period of time ranging from a time prior to introduction of the test strip into the optical meter to a time after application of the sample to the sample application location. In other words, the means for collecting reflectance data is such that it collects reflectance data from the specified region of the meter prior to the insertion of a test strip into the meter.

Furthermore, Claims 11, 12 and 14 specify means for comparing the above-described collected reflectance data to a reference value to obtain a sample present signal. The specification describes such means as follows:

Atty Dkt. No.: LIFB-009
USSN: 09/630,340

This comparison step may be performed manually or by a suitable automated data processing means, e.g. a computing means made up of suitable computing hardware and software. The above comparison step yields a sample present signal.
(page 7, lines 22-25) (Emphasis added.)

In addition to the above means for obtaining reflectance data, the subject meters also generally include a means for comparing the reflectance data to a control value reference, as described above, to obtain a sample present signal. This means is generally a data processing means, such as a computing means made up of appropriate computing hardware and software, for comparing the reference data to the reference and generating a sample present signal.

(page 11, lines 10-15) (Emphasis added.)

The reflectance data as represented in Fig. 6E is then compared to a reference to obtain a sample present signal...
(sentence bridging pages 13 and 14)

Accordingly, the subject claims specify means that take reflectance data collected from a region of the meter occupied by a sample application location of a test strip when present in the meter, which data includes reflectance data collected over a period of time ranging from a time prior to introduction of the test strip into the optical meter to a time after application of the sample to the sample application location, and compares this data to a reference value. As noted above, such means may generally be described as computing means that includes suitable computing hardware/software. In other words, this computing means of the claimed meter compares reflectance data as represented in FIG. 6E to a reference to obtain a value.

However, the cited reference does not collect reflectance data from a region of the meter occupied by a test strip application location when present in the meter prior to insertion of a test strip into the meter, as the cited reference teaches means, e.g., detector system 42, that collects reflectance data from a time after the test strip has already been inserted into the meter (see for example col. 7, lines 11-19). The Examiner states that the cited reference teaches that when sample is introduced at the sample application area, a reduction in reflected light to the detector occurs, thus inherently detecting reflected light prior to sample being present at the sample application zone. However, the Applicants respectfully submit that in order to provide the reduction of reflected light referred to by the Examiner,

Atty Dkt. No.: 1.IPI-009
USSN: 09/630,340

as also noted by the Examiner light must be collected prior to the introduction of sample to the application site- not prior to the introduction of the test strip into the meter.

Consequently, as the cited reference does not teach means for the collection of reflectance data as claimed in Claims 11, 12 and 14, this reference cannot teach computing means for comparing this collected reflectance data (i.e., collected reflectance data from a region of the meter occupied by a test strip application location when present in the meter prior to insertion of a test strip into the meter (that which is represented in FIG. 6E)) to a reference value to obtain a sample present signal. Stated otherwise, computing means for comparing reflectance data collected in accordance with the cited reference would not be the same as computing means for comparing reflectance data collected in accordance with Claims 11, 12 and 14.

The Examiner asserts that the recitation of the period over which reflectance data is collected is considered to be the manner in which the means for collecting reflectance data operates and thus does not distinguish the claims over the cited reference. However, at least in regards to specified means for comparing collected reflectance data to a reference value to obtain a sample present signal, the Applicants respectfully submit that the cited reference does not include all of the structural limitations of the claimed means as it at least does not include suitable computing means for accomplishing this.

As such, for at least the reasons described above, Shartle does not anticipate Claims 11, 12 and 14. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Rejection under 35 U.S.C. §103(a)

Claims 13, 15-19 and 21 have been rejected under 35 U.S.C. §103(a) as obvious over Shartle in view of Saunders et al. (US Patent 5,674,699). The Examiner asserts that Shartle teaches all of the claimed elements except Shartle does not teach any particular wavelength to use in irradiating the test strip. The Examiner states that such is provided by U.S. Patent No. 5,674,699 issued to Saunders et al. (hereinafter referred to as "Saunders"). The Examiner contends that it would have been obvious to one of skill in the art in view of Saunders to use a wavelength suitable for reflecting light from the particular sample being deposited on the test strip in conducting the method of Shartle. As described above, Claims 19 and 21 have been cancelled. In regards to Claims 13, and Claims 15-18, the Applicants submit that the cited reference does not anticipate these claims.

The Applicants respectfully submit that the cited references, either alone or in combination, fail to teach or suggest all of the claim limitations. As described above, Shartle fails to teach or even suggest a meter that obtains reflectance data for a period of time ranging from a time prior to introduction of a

Atty Dkt. No.: LIFE-009
USSN: 09/630,340

test strip in the meter to a time after application of the fluid sample to the sample application location and thus fails to teach or suggest means for comparing such reflectance data to a reference value to obtain a sample present signal, as claimed in Claims 13 and 15-18.

As Saunders is cited solely for its teaching relating to the determination of the particular wavelength at which a particular assay should be conducted to maximize results, Saunders fails to make up for the deficiencies of Shartlc.

Accordingly, for at least the reasons described above, the cited combination of references fails to render Claims 13 and 15-18 obvious.

Atty Dkt. No.: LIFE-009
USSN: 09/630,340

CONCLUSION

In view of the above amendments and remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issuance. The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, Order No. LIFE009.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: 8/19/03

By: _____
Susan Tall
Registration No. 52,272

BOZICEVIC, FIELD & FRANCIS LLP
200 Middlefield Road, Suite 200
Menlo Park, CA 94025
Telephone: (650) 327-3400
Facsimile: (650) 327-3231

F:\DOCUMENTS\francis\sp to ua\05-19-03.doc

OFFICIAL

FAX RECEIVED

AUG 20 2003

TC 1700

LFS-076